Please amend claim 22 as follows: In line 2, after "or" delete "pharmaceutically acceptable derivatives" and insert " a pharmaceutically acceptable derivative" therefor.

In view of the above amendments and following remarks, reconsideration and allowance of the application is hereby respectfully requested.

REMARKS

Applicant wishes to thank the Examiner for the time and courtesy extended during the telephone conference of June 19, 2002.

Restriction Pursuant to 35 U.S.C. § 121

Restriction to one of the following inventions has been required by the Examiner:

Group I Claims 1-19, drawn to a composition, classified in class 514, subclass 634; and

Group II Claims 20-35, drawn to a method of use, classified in class 514, subclass 634.

The inventions of Group I and Group II are related as a product and process of use

and are allegedly distinct pursuant to M.P.E.P. § 806.05(h) in that the product can be used in a materially different process of using the product, namely the product can allegedly also be used as a hypertensive agent. Applicant respectfully traverses the rejection.

The inventions of Group I and Group II are classified in the same class and subclass, namely class 514, and subclass 634. Thus, the inventions of Group I and Group II can be examined together without producing any undue burden upon the Patent and Trademark Office. In addition, the composition, as claimed in independent claim 1, is comprised of a pharmaceutically effective amount of a guanidine derivative suitable for use in providing a rapid onset and long lasting analgesia and sedation (chemical restraint) in an animal which is separate and distinct from compositions useful as hypertensive agents.

However, to enhance the efficient prosecution of the application to issue, applicant has canceled claims 1-19 (Group I) without prejudice and hereby reserves the right to pursue those claims in a related divisional application. Thus, following the amendment above canceling claims 1-19, claims 20-35 (Group II) are pending in the application for examination on the merits.

Objection Under 37 C.F.R. § 1.75(c)

The Examiner's objection to claims 8-15 under 37 C.F.R. § 1.75(c) has been rendered moot in the instant application by the cancellation without prejudice of claims 1-19.

Rejection Under 35 U.S.C. § 112, second paragraph

The Examiner's rejection of claim 3 under 35 U.S.C. § 112, second paragraph has been rendered moot in the instant application by the cancellation without prejudice of claims 1-19. The rejection of claim 22 is believed to be overcome with the above-amendment of claim 22. In particular, claim 22 has been amended consistent with the Examiner's suggestion on page 2 of the Office Action, namely to change "pharmaceutically acceptable derivatives" to " a pharmaceutically acceptable derivative." A "VERSION WITH MARKINGS MADE TO SHOW CHANGES" (page 9) and an "AMENDED VERSION WITHOUT MARKINGS" (page 10) of amended claim 22 is being submitted concurrently herewith. In view of the amendment of claim 22, withdrawal of the § 112, second paragraph rejection is believed to be warranted and is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

The Examiner's rejection of claims 1-19 under 35 U.S.C. § 103(a) is rendered moot in the instant application by the cancellation without prejudice of claims 1-19.

Claims 20-35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,635,204. The Examiner alleges that the '204 reference discloses a method of inducing sedation and analgesia using the instant guanidine derivatives and that the claims differ over the reference in requiring specific routes of administration, subjects and dosages. The rejection alleges that it would be within the scope of the artisan to determine optimum routes of administration, subjects and dosages. Applicant respectfully disagrees.

The '204 patent is directed to the use of a *required combination* of drugs to induce *general anesthesia* or a surgical stage of anesthesia. For example, the specification of the '204 patent at column 2, lines 9-23 specifically recites the required combination of drugs for induction of general anesthesia, namely fentanyl or a fentanyl analog (line 12); an α_2-adrenergic agonist such as clonidine (lines 13-16); and an amnesia inducing drug such as ketammine (lines 17-19). In fact, the claims of the '204 patent require a two step

administration of drugs of the required combination to produce the general or surgical anesthesia. For example, claim 1 (column 5, lines 37-45) teaches a first step consisting of the transdermal administration of an amnesia producing drug (*e.g.*, ketamine) and a second step consisting of the administration of a *combination* of clonidine (an α_2-adrenergic agonist) and fentanyl which occurs after the induction of an amnestic state. Likewise, claim 9 of the '204 patent is directed to a method of inducing anesthesia in a mammal using the transdermal administration of a combination of clonidine and a fentanyl analog.

There is absolutely no teaching or suggestion anywhere in the '204 patent of a method of rapid induction of long lasting sedation and analgesia in an animal via administration of a single guanidine derivative as set forth in independent claim 20. Likewise there is certainly no teaching or suggestion of induction of the rapid onset sedation and analgesia in a standing animal as set forth in dependent claim 28.

General or surgical anesthesia certainly increases the risk to the patient and, as set forth in the '204 patent, *requires* administration of additional drugs, namely narcotics and dissociative anesthetic agents such as fentanyl and ketamine respectively, which increase the risk of adverse reactions in the patient. The methods of the instant application do not require administration of any agent other than a guanidine derivative for induction of the

desired sedation and analgesia and cannot be obvious in view of the teachings of the '204 patent. Withdrawal of the rejection of claims 20-35 under 35 U.S.C. § 103(a) is therefore believed to be warranted and is earnestly solicited.

Related Matters

During the telephone conference of June 19, 2002, it was noted by applicant that an Information Disclosure Statement had been submitted prior to the mailing of the first office action, namely on December 17, 2001. However, in view of the fact that additional references disclosed in the IDS have not been considered by the Examiner and also due to applicant's desire to present additional data in support of the application, the Examiner has consented to conduct an interview as soon as mutually convenient. The undersigned attorney will contact the Examiner to schedule the interview. In the interim, as requested a courtesy copy of this amendment is also being faxed to the Examiner at (703) 746-5317.

The Commissioner is hereby authorized to debit deposit account number 11-0978 for the $460.00 fee for the three month extension of time. No additional fee is believed to be due, however, the Commissioner is hereby authorized to debit or credit deposit account

number 11-0978 for any additional fees deemed to be due or issue a credit for any overpayment thereof.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on _____

J.W. Seanor DVM

Date June 19, 2002

VERSION WITH MARKINGS MADE TO SHOW CHANGES

22. (Amended) The method of claim 20, wherein the guanadine derivative is guanabenz acetate or a pharmaceutically acceptable derivative ~~derivatives~~ thereof.